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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,393	10/05/2004	Britta Evers	X-15555	2443
25885 7	590 07/20/2006		EXAMINER	
ELI LILLY & COMPANY			STOCKTON, LAURA LYNNE	
PATENT DIVISION P.O. BOX 6288			ART UNIT	PAPER NUMBER
INDIANAPOLIS, IN 46206-6288			1626	
C		DATE MAILED: 07/20/2000	6	

Please find below and/or attached an Office communication concerning this application or proceeding.

<u> </u>	•	Application No.	Applicant(s)				
Office Action Summary		10/510,393	EVERS ET AL.				
		Examiner	Art Unit				
		Laura L. Stockton, Ph.D.	1626				
	- The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period fo	Period for Reply						
WHIC - External after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It is period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONEI	I. sely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status							
1)🖂	Responsive to communication(s) filed on Octob	ber 5, 2004 (Preliminary Amendm	<u>nent)</u> .				
2a) <u></u>	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositi	ion of Claims						
4)⊠	4)⊠ Claim(s) <u>1-20 and 23-25</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.							
	5) Claim(s) is/are allowed.						
6)⊠	6)⊠ Claim(s) <u>1-20 and 23-25</u> is/are rejected.						
7)	7) Claim(s) is/are objected to.						
8)	Claim(s) are subject to restriction and/or	election requirement.					
Applicati	Application Papers						
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	ınder 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a)⊠ All b)☐ Some * c)☐ None of:							
	1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No						
	3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
			•				
Attachmen	t(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)							
2) Notic	te						
	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date <u>10/5/2004</u> .	5)  Notice of Informal Pa	atent Application (PTO-152)				

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#### DETAILED ACTION

Claims 1-20 and 23-25 are pending in the application.

#### Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on October 5, 2004.

### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple

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assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 and 37-74 of copending Application No. 10/510,305 and claims 1-28, 30-39 and 41-46 of copending Application

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No. 10/380,867, now allowed. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention is generically claimed in each of the copending applications. See, for instance, the specie in claim 39 in copending Application No. 10/510,305 and the species of claim 46 of copending Application No. 10/380,867.

The indiscriminate selection of "some" among "many" is prima facie obvious, <u>In re Lemin</u>, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., modulation of endogenous growth hormone levels).

One skilled in the art would thus be motivated to prepare products embraced by each of the copending applications to arrive at the instant claimed products with the expectation of obtaining additional beneficial products that would modulate endogenous growth hormone

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levels. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 23 and 25 are rejected under 35
U.S.C. 112, second paragraph, as being indefinite for
failing to particularly point out and distinctly claim

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the subject matter which applicant regards as the invention.

In claim 3, under the definition of R3, an "or" should be added before "substituted  $C_1-C_6$ alkyl(0)- $C_1-C_6$ alkylaryl".

Claim 23 should be re-written to reflect that the claim is directed to "A method for treating" and not "A method comprising administering".

In claim 25, the phrase "selected from the group consisting of" should be changed to "which is".

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>(</sup>a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 1-18 and 23-25 are rejected under 35
U.S.C. 103(a) as being unpatentable over Dodge et al.
{WO 2002/32888}.

# Determination of the scope and content of the prior art (MPEP \$2141.01)

Applicants claim isothiazolidine and pyrrolidone compounds. Dodge et al. teach isothiazolidine and pyrrolidone compounds which are structurally similar to the instant claimed compounds. See, for instance, Formula I on pages 4-6, the process of instant claim 18 on page 25; and especially Example 1 on page 44.

## Ascertainment of the difference between the prior art and the claims (MPEP \$2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

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Finding of prima facie obviousness--rational and motivation (MPEP \$2142-2413)

The indiscriminate selection of "some" among "many" is prima facie obvious, <u>In re Lemin</u>, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., modulation of endogenous growth hormone levels).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products that would modulate endogenous growth hormone levels. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be

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directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620 Technology Center 1600